M E M O R A N D U M

Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Biologics Evaluation and Research

To: File of STN 125197/0
Device: ----(b)(4)----------
Sponsor: Dendreon Corporation

From: Valerie Coleman, Software Reviewer, Devices Review Branch

Subject: BLA Software Review Memo

Through: Linda Weir, BECS Expert, Devices Review Branch
Teresita C. Mercado, Chief, Devices Review Branch

Background:

I performed the software consult review for --------(b)(4)---------- from Dendreon Corporation. The submission consisted of a 118 page amendment from the firm labeled, 1.6.3, Response to Request for ---(b)(4)----- Information. This document was in response to issues discovered during the January 25-29, 2010 FDA inspection of the firm. I received the software documentation on January 15, 2010, February 12, 2010 and February 19, 2010. Although the documents referenced two other systems: ---------(b)(4)---------- and Laboratory Information Management System (LIMS), these systems were not included as a part of the consult request from OCTGT.

Level of concern:

The software is a minor level of concern software.

Intended Use:

----------(b)(4)---------- that is used to schedule resources used for ordering, manufacturing, and delivering sipuleucel- T and communicate planned and actual times for such activities.

Device Description:

---(b)(4)------ is a scheduling tool that:

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Review Documentation-Additional Information Requested from the Firm:
Review of the submission required additional information from the firm before a recommendation could be made. FDA sent a letter requesting additional information to the firm on March 4, 2010. The firm requested a teleconference to discuss the intended use of ---(b)(4)--- that was held on March 5, 2010. On March 15, 2010, this reviewer received a 491 page response titled BLA STN 125197/0, Amendment No. 0043, dated March 10, 2010. The responses were adequate. The response contained a risk assessment table that identified several elements that the firm classified as a high risk priority; none of the elements appear to be clinically significant.

Items Reviewed;
- Level of concern
- Intended Use
- Risk Assessment
- Software Description
- Functional Requirements
- Traceability Matrix